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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,148	02/01/2002	Marie-Cecile Van de Lavoie	271/123	4804

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34

Office Action Summary

Application No.

10/067,148

Applicant(s)

VAN DE LAVOIR ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,26-30,41-48,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,26-30,41-48,51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/28/04.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's response filed on 04/28/04 has been acknowledged.

Claims 21, 26-30, 41-52 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised **37 CFR §1.121**. The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 26-30, 41-48 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pain et al (Development 122:2339-2348, 1996, ref of record) in view of Gibbins et al (Pro. 4th World Congress on Genetics applied to livestock production XVI, 118-122, Edinburg 1990, ref of record).

The instant claims are drawn to a chimeric chicken or method of making the same wherein the chimeric chicken comprised of progeny of embryonic stem cells.

Pain teaches in-vivo differentiation of chicken embryonic stem cells (CEC) obtained from **long-term in-vitro culture**. Cited art further teaches irradiated cultured CEC obtained from Barred Rock black strain CEC were injected into the subgerminal

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cavity of stage X White Leghorn recipient embryos, which resulted in the hatching of chimeric plumage phenotypes (see claims 21, 41, 43-44). The cited art further teaches that regardless number of passages more than 50% of the hatched recipient embryos were chimeras with nearly 33% of plumage from donor phenotype (page 2344 col.2 para.2; page 2346, fig-8). The cited art further teaches CEC expressing ECMA-7, SSEA-1 and EMA-1 could be cultured for at least 35 passages i.e. more than 160 days in the presence of LIF, a cytokine (page 2343 col. 1-2, fig-4). Regarding claims 26-30 and 45-48 and 51-52, the cited art teaches that it is well known in the art that cells derived from early chicken blastoderm will contribute to both somatic and germ line when injected into recipient embryos to form chimeras (page 2339, col.2 para.2). The cited art further teaches that long-term cultured CEC were capable of differentiating several lineages, which could be characterized lineage marker specific antibodies (page 2344 col. 1 para. 3).

However Pain et al does not teach the genetic modification of embryonic stem cells prior to the injection into the recipient embryo.

Gibbins et al teaches efficient transfer of chicken blastoderm cells and their incorporation into recipient embryos to produce chimeric chickens. The cited art teaches that isolation and culture of pluripotent embryonic stem cells and transfection of these cells with DNA constructs using Lipofectin. The cited art further teaches selection of stably transfected cells and introduction of the transfected cells into a recipient embryo to generate chimeric birds (page 120, paras 2-3). The cited art further teaches successful construction of chimeric birds from several different donor/recipient line combinations indicating that the technique should have broad applicability across breeds (page 121, para.2).

Thus it would have been obvious to one ordinary skill in the art at the time the instant invention was made to modify the teaching of Pain with Gibbins by substituting the embryonic stem cells with genetically modified stem cells in order to make chimeric chickens. One would have been motivated to do so to make transgenic birds by cross breeding the chimeric chickens. One would have a reasonable expectation of success, since making chimeric birds that encodes a transgene has been routine in the art at the

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time of filing. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

Response to Declaration

The applicant argues that Pain et al (Development 122, 2339-2348, 1996) only describes chimeric chickens developed from embryonic stem cells maintained in culture for a maximum period of 19 days. The applicant argues that in contrast, the instant application describes the development of chimeric chickens from an embryonic stem cell culture that is maintained for more than 60 days. The applicant argues that the significance of this time period is that it allows the time necessary to transfect, select, and isolate ES cell lines carrying a stably integrated transgene into the genome of the embryonic stem cells held in culture. The applicant argues that it would not have been expected that the chicken embryonic stem cells could be maintained in culture for a period of time long enough to be transformed such that a transgene was stably integrated into the genome of the cells and the cells maintained the embryonic stem cell characteristics (declaration page 2).

However, applicant's arguments are found NOT persuasive. Pain et al clearly teaches in-vivo differentiation of chicken embryonic stem cells (CEC) obtained from long-term in-vitro culture for up to 60 days. The cited art further teaches that regardless number of passages more than 50% of the hatched recipient embryos were chimeras with nearly 33% of plumage from donor phenotype (page 2344 col.2 para.2; page 2346, fig-8). The cited art specifically teaches culture conditions (containing LIF) that are necessary for long-term in-vitro growth of CEC with ES-like marker (page 2343, col.1, fig-4). The cited art clearly established that cultures maintained in the presence of LIF progressively selected more homogeneous population of cells ECMA-7 and ECMA-1 embryonic stem cell markers. The cited art further teaches that the CEC expressing ECMA-7, SSEA-1 and EMA-1 could be cultured for at least 35 passages i.e. more than 160 days in the presence of LIF, a cytokine (page 2343 col. 2, lines 16-25). Therefore Pain et al clearly establishes that the CEC could be cultured for at least 35 passages i.e. more than 160 days, while maintaining chicken embryonic stem cell characteristics.

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In addition, if the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In instant case the chimeric chicken (as claimed) is indistinguishable from the cited art of record, since one skill in the art would NOT be able to differentiate the chimeric chicken as claimed herein from the chimeric chicken disclosed in the prior art of record. The genome of the chicken embryonic stem cells would be same even after long-term culture of 160 days, while maintaining the expression of antigens characteristic of chicken ES cells (see page 2343 col.2). Thus the invention as claimed is obvious over the cited prior art of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Sumesh Kaushal
Examiner GAU 1636


JEFFREY FREDMAN
PRIMARY EXAMINER


